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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,835	08/25/2000	Scott Koenig	469201-493	4179

7590 12/24/2002
Alan J Grant
Carella Byrne Bain Gilfillan Cecchi Stewart &
Olstein
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/24/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/645,835

Applicant(s)

KEONING ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-30 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 is/are ~~allowed~~ free of art of record.
- 6) ☒ Claim(s) 25-30 and 33-35 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 9-30 and 33-37 are pending.

Applicants' amendment and response filed on October 10, 2002 (Paper No. 16) has been entered and fully considered. Claims 9-24 remain withdrawn from consideration. Claims 25-28 and 33-37 have been amended, thus claims 25-30 and 33-37 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 25-30 and 33-36 under 35 U.S.C. 112, second paragraph, regarding the term "at least 75% (90% or 95%) identical to the sequence of SEQ ID NO:4 (or SEQ ID NO:2)" or "at least 25% identical to the sequence of the Sp36 protein", or the amino acid sequence of Sp36 is not identified with a "SEQ ID NO:", is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in Paper NO. 16.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25-28 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25-28 and 33-35 are directed to a polypeptide comprising an amino acid sequence having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:4, wherein the polypeptide reacts with an anti-pneumococcal Sp36 antibody (claims 25-27); to a polypeptide comprising an amino acid sequence having at least 75% sequence identity to SEQ ID NO:2 or 4, wherein the polypeptide is present in an organism of Group A streptococci or *Staphylococcus aureus* and the polypeptide reacts with an anti-pneumococcal Sp36 antibody (claim 28); or to a polypeptide comprising an amino acid sequence having at least 75% sequence identity to SEQ ID NO:2 or 4 or having 90%, or 95% sequence identity to SEQ ID NO:2, wherein the polypeptide has a sequence with at least 25% sequence identity to Sp36 protein of *Streptococcus pneumoniae* (SEQ ID NO:7) (claims 33-35). The specification indicates that the polypeptide which have at least 70%, 90% or 95% sequence identity to the reference polypeptide (page 11, lines 12-16) can be used as a vaccine (page 22, lines 7-10). The specification further asserts that antiserum raised against the pneumococcal Sp36 protein cross-react with Sp36 homolog identified from the group B streptococci and indicating conservation of epitopes between the polypeptides (Example 4). However, the specification does not specify which portion of the polypeptide is identical to SEQ ID NO:4 or 2 and reacts with an anti-pneumococcal Sp36 antibody, nor indicates how specific the reaction between the antibody and the polypeptide; and which portion of the polypeptide is identical to SEQ ID NO:4 or 2, and SEQ ID NO:7. There is no disclosure indicating the sequences having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:2 or 4 are reacting with anti-pneumococcal Sp36 antibody specifically. Without guidance for structure to function/activity, one skilled in the art would not know which region or residue of SEQ ID NO:2 or 4 is essential for function/activity and how to identify a functional polypeptide. The lack of a

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structure to function/activity relationship and the lack of representative species for the polypeptides having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:2 or 4 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

4. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

5. Claims 25-30 and 33-35 are rejected, and claim 36 is objected. It appears claim 37 is free of art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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December 17, 2002